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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,778	04/09/2004	Tomas Kara	630666.91161	1444
26710	7590	12/14/2005		
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497			EXAMINER AGUEL, FERNANDO	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,778

Applicant(s)

KARA ET AL.

Examiner

Fernando Aguel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 21-29 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/30/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of a method of group I in the reply filed on 10/28/05 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 8/30/04 is noted. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 2 recites the limitation "elongating the vagus nerve signal.". There is insufficient antecedent basis for this limitation in the claim. It is suggested that applicant change the word "elongating" to "prolonging".
5. Claims 2 and 5 recite the limitation "vagus nerve signal.". There is insufficient antecedent basis for this limitation in the claim. It is suggested that applicant change "vagus nerve signal" to "vagus nerve stimulation signal".
6. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "isolating the detected vagus

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nerve signal from the filtered vagus nerve signal and the prolonged vagus nerve signal."

Does applicant mean electrically isolating? Does applicant mean filtering? Or does applicant mean maintaining the signals separately?

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 21-24, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio et al. (6341236) in view of Adkins et al. (5928272). Osorio et al. disclose detecting vagus nerve stimulation, digitizing the signal, filtering the signal and rectifying the signal (fig 10, col. 11, lines 18 – 39) but do not disclose amplifying the signal nor prolonging the signal nor electrically isolating the signal nor comparing the

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filtered and rectified signal to a threshold value nor detecting an analog signal such as ECG. Osorio et al. do not disclose triggering the sampling of a physiologic signal such as ECG. Adkins et al. teach amplifying a sensed signal from vagus nerve stimulation, and comparing the value to a threshold value (col. 8, line 52 – col. 9, line 6). Adkins et al. also teach triggering the sampling of a physiologic signal including ECG (col. 6, lines 54 – 67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Osorio et al. by amplifying the VNS signal in order to achieve higher resolution when converting to digital form and to compare the signal to a threshold value in order to objectively determine whether VNS was taking place and to trigger the sampling of ECG after the detection of VNS in order to assure that physiologic function of the heart is unaltered, in which case the ECG would be a function of the VNS since the vagus nerve innervates the heart.

10. It is well known in the art to prolong the signal when converting a signal to digital form for later sampling and would have been obvious to one of ordinary skill in the art to prolong the signal in order to choose different sampling rates that exactly those used by the A/D converter since sometimes A/D converters use variable sampling rates.

11. It is well known in the art to isolate sensed signals in order to prevent inadvertent shocking of the patient through the sensing circuit. It would have been obvious to one of ordinary skill in the art to isolate the sensed signal in order to prevent inadvertent shocking of the patient.

12. Claims 5, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio et al. (6341236) in view of Adkins et al. (5928272) as applied to claim 1 above,

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and further in view of Lo et al. (5738104). Osorio et al. and Adkins et al. disclose the invention substantially as claimed but do not disclose an alarm signal indicating that the VNS has been detected, nor storing the physiological signal as a function of time nor displaying the physiologic signal and the filtered signal. Lo et al. teach an ECG machine with a display (fig 1, element 12) which could display fig. 11A, 11B and 11C from Osorio et al. (6341236) which is interpreted to be a visual alarm signal as well as the displaying of the filtered and physiologic signals and Lo et al. is configured to store what was displayed in memory (col. 15, lines 7-27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Osorio et al. and Adkins et al. by including the display for displaying the physiological signal as well as the filtered signal and storing these signals in order to visibly inspect the signal measured as well as review the signals measured at a future point in time by a physician.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Patton et al. (4989610)

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fernando Aguel whose telephone number is 571-272-8687. The examiner can normally be reached on M-F, 8:30-5:00.

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15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FA
Fernando Aguilar
12/12/05

George Manuel
George Manuel
Primary Examiner